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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HARTLEY, MICHAEL G

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 08/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/446,328

Applicant(s)

SPECK ET AL.

Examiner

Michael G. Hartley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Response to Arguments

Applicant's arguments filed 7/8/2002 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38-41 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons set forth in the office action mailed 12/31/2001.

Applicant asserts that one of ordinary skill in the art would have recognized possession of the claimed classes of compounds, such as, those defined by negative limitations.

This is not found persuasive because the negative limitations set forth in the claims encompass a huge and undefined set of compounds, which are for use as contrast agents in the instant invention. On the other hand, the specification describes the use of specific contrast agents. But it fails to describe the use of contrast agents which are "non-polymer," "non-peptide," "monomeric non-ionic iodine containing" or "dimeric non-ionic iodine containing". Such recitations (e.g., non-peptide) to describe a contrast agent would include any compound that is not made up of repeating units of amino acids. Clearly, one of ordinary skill in the art would not have seen possession of any compound, just as long as it is not a protein, for use as a contrast agent in the methods of imaging as claimed. There is nothing in the specification to show applicant envisioned these broad, undefined classes of contrast agents, since there is no mention thereof in the specification of such broad classes of contrast agents. The skilled artisan would not have recognized that any "non-peptide" or "non-polymer" could be used as a contrast agent with the description of specific contrast agents as defined by the claims. Further, the skilled artisan would not have recognized possession of these specific exclusions or negative limitations by the description of the use of the specific contrast agents in the disclosure. Any negative limitation must have basis in the original disclosure. See *Ex parte Grasselli*, 231 USPQ 187, 196 (CCPA 1977).

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 18 is rejected under 35 U.S.C. 102(e) as being anticipated by Galkin (US 5,844,965), for the reasons set forth in the office action mailed 12/31/2001.

Applicant asserts that the reference only discloses the possibility of using contrast agents and that such a method was not performed, as there is no example in the reference of such use.

This is not found persuasive because patents are relevant as prior art for all that they contain. Galkin clearly states that the invention includes the use of contrast agents in mammography imaging, as can be seen from column 4, lines 44-64. One of ordinary skill in the art in reading this patent would have immediately envisaged a method of mammography using a contrast agent in the passage of column 4, lines 44-64. While the patent contains no actual examples of imaging, both mammography and the use of contrast agents are so well known, that the disclosure that the invention includes a method of mammography with the use of a contrast agent clearly provides an enabling disclosure and provides a teaching of such a method to one of ordinary skill in the art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Galkin (US 5,844,965) or Nitecki (US 5,756,006) in view of Chang (Radiology), Ranney (US 5,260,050),

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Hilger (US 5,849,259), Brasch (US 6,009,342), Kirpoitin (US 5,411,730) and Platzek (US 6,054,117), for the reasons set forth in the office action mailed 12/31/2001.

Applicant asserts that Galkin and Nitecki only mention methods of contrast agent in a general sense, thus do not provide sufficient instruction to lead one of ordinary skill in the art to use a contrast agent in mammography as claimed.

This is not found persuasive because Galkin solely deals with mammography and discloses that an improvement therein is gained by the use of a contrast agent. Also, Nitecki is specifically related to novel contrast agents for methods of imaging (see abstract) and specifically discloses that they are useful for mammography, "as well as use in lymphography and mammography" (see column 2, lines 34-35). Clearly, one of ordinary skill in the art would have been motivated to employ the contrast agents in mammography by such a direct teaching thereof. The use of the contrast agents in mammography is not in a large "laundry list" but is provided in a direct, limited teaching of a few diagnostic methods in which the contrast agents are useful, "lymphography and mammography." Upon reading this passage in column 2, lines 31-35, one of ordinary skill in the art would have at once envisaged the use of the contrast agent for methods of mammography. Further, since both mammography and the use of contrast agents are well known, the skilled artisan would have had clear instruction on the use of a contrast agent in mammography from these disclosures.

In response to applicant's argument that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991).

It is noted that only Galkin and Nitecki are used to teach methods of mammography using various contrast agents, e.g., radiographic contrast agents, while the other cited references are used to show that the various contrast agents claimed are known in the art to be equivalent or improved contrast agents for X-ray imaging.

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Conclusion

No claims are allowed at this time.


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose G. Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Michael G. Hartley
Primary Examiner
Art Unit 1616

MH
August 7, 2002